“Lupin Limited Q3 FY2022 Earnings Conference Call”

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MANAGEMENT:

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Moderator: Welcome to Lupin Limited Q3 FY22 Earnings Conference Call. Please note, all participants line, will be in listen-only mode, and there will be an opportunity for you to ask questions after the opening remarks. Please note that this conference is being recorded. I now hand the conference over to management. Thank you, and over to you.

Kamal Sharma: Thank you. Good evening, friends. It's a pleasure for me to welcome you to this Q3 earnings call. As you would have seen by now, overall another difficult quarter for the company, despite some good developments, like the sales growth in the U.S.. However, I do believe that with some of sound learnings and substantial strengthening, and a number of optimization initiatives underway, we are going to see much better times in the coming quarters and we're all looking forward to that, and I'm sure you too are looking forward to that, with that brief introduction, I would now hand you over to our CFO Mr. Ramesh Swaminathan for detailed analysis. Thank you, and over to you Ramesh.

Ramesh Swaminathan: Thank you. Dr. Sharma and good evening, friends. Trust you and your family are keeping good in these troubled times. Revenue for Lupin grew 2% quarter-on-quarter, driven primarily by U.S growth of 10.4%, driven in turn by, strong growth of albuterol, where we now have a 20% market share. Year-on-year, we registered 4.3% growth, driven by majority of our markets, U.S. 9%, and IRF 12% (overall India region 8%), along with others like Australia 13%.

Gross margins were down by 0.9% QoQ primarily due to increase in the input material cost, sales mix, and higher U.S. sales. Employee cost is down 2%, quarter-on-quarter at 18.2% of net sales, primarily due to the savings realized, with the specialty restructuring in the U.S.. This despite providing for additional sales incentives in India linked to performance.

Manufacturing and other expenses were higher by 18.3%, quarter-on-quarter, primarily due to the one-time charge of about $26 million or INR193 crores. We reviewed U.S. provisions and determined that there was a need to further increase the same, to properly reflect the impact of some one-time items, that we experienced over the last two years. That is the unusual high volumes returns from a 2020 patient level recall of Metformin and slow-moving flu medication at wholesalers' warehouses.

Other income is down 53%, primarily due to interest on tax refund, earned in quarter two, and this is obviously not there in quarter three. EBITDA adjusted for the one-time charge of $26 million or INR193 crores, was at INR564 crores flat quarter- on- quarter. The adjusted EBITDA of 13.7% versus 14.1% sequentially.

Given the exceptional items taken at Lupin standalone accounts, the bottom line for the first nine-months comes up negative, warranting a write back of the taxes provided till date. The ETR for the full year, for the company should be about 30% to 32%. Given the tax being paid in certain geographies, despite the lower PBT on a consolidated basis.

For the next two to three quarters, we see margin slowly moving up in the 14% levels. The next couple of quarters, EBIDTA improvement will come largely from the optimization efforts and there are several initiatives in advanced stages, including tight management of FTS, our returns, write-offs, freight charges and plant idle cost. Some of the near-term drivers of

growth, are going to be Suprep, Peg G-CSF, Tiotropium and growth in India and other geographies.

We see meaningful uptick in H2 FY23 and then FY24, we see the real growth drivers kicking in, with full impact of our inhalations' portfolio, injectables' portfolio, and biosimilars which will deliver higher numbers and commensurate gain to the margins and EBITDA levels to move up to about 20% plus. Friends would also be happy to know that, we have completed our acquisition of a Bolt-on in Australia, called the Southern Cross. And further add the numbers going forward, I'll tell you the full story and other issues, I would open the floor for discussions. With this, may I open the floor for the discussions.

Moderator: Thank you. We will now begin the question-and-answer session. First question is from Anubhav. Please, unmute yourself.

Anubhav Agarwal: Yes. Hi, guys, good evening. This is Anubhav from Credit Suisse. Just one question on the next two years. So just for the timing, if you assume that you will not going to launch Tiotropium and Suprep and I'm talking about next two years and if I classify rest of the business as base business. Can you just talk about how would the gross margin and the EBITDA margin pan out for this part of the business over next two years?

Vinita Gupta: Ramesh, you want to take it or you want me to take it?

Ramesh Swaminathan: You could take it first and I could add Vinita.

Vinita Gupta: Yes. So Anubhav, we see that your question is about the baseline business versus new product launches - what will it contribute? We expect baseline business margin also to improve over the next couple of quarters, even if you assume FY23 just the baseline products with the optimization efforts that we have already executed as well as the ones that are on the angle for implementation. We see the potential of improving our gross margins offsetting some price erosion as well with the plans that we have.

Anubhav Agarwal: Just some clarity on that. Where will gross margin improvement come from, because one is from regional gross margin improvement, second is product level launch. So, we have very good products coming in, except the Tiotropium and Suprep, I'm not aware of very high value other product, which are helping in. So that's why I was asking that one, Your efforts on reducing cost can help the EBITDA margin on the operating leverage side, but I'm not able to understand from where will our gross margin improvement come from.

Vinita Gupta: Yes. Go ahead, Ramesh.

Ramesh Swaminathan: There are couple of things, so even during the course of the year, we have taken some exceptional items in the netting off from sales itself, which includes some parts of returns and for sure provisioning and the like. And these as you would recognize are not something which will actually occur in the long-term, in the future as well. And to that extent, we certainly see a blip-up coming up in so far as gross margins are concerned.

In terms of other cost, we have identified several pockets where we have invested ahead of the curve in the past, as in capacities, in terms of SG&A and the like, and over the next few quarters we would like to work on all of that and address it, a meaningful movement upward actually come from those as well. So, to that extent, the confidence level of taking the EBITDA margins up is coming from there.

Nilesh Gupta: So, Ramesh, if I can just add here, so, I think the question is on the gross margin line, right. So, on the gross margin line and above it's the business mix, right now obviously the U.S. has grown, India has actually degrown relative to this. So, as that mix changes again in Q1, Q2, you would see gross margin improving as well. Obviously, there's also a story around operating leverage and the like there. But on the gross margin, I think it will be primarily driven by the business mix.

Anubhav Agarwal: Great. And thanks. Second question is, just a clarity on the U.S. So roughly analyze level of $800 million, very ballpark number. What percentage of our U.S. revenues will be contributed by partner and AG products, very rough number will do. I'm just trying to understand why our gross margin so low.

Vinita Gupta: Roughly 20%.

Anubhav Agarwal: 20%. Okay. That's helpful. And just last question on the Tiotropium. So can you just indicate, where is your application with FDA? When did you reply back to FDA? How long has it been sitting with FDA now? And when you expect the approval?

Vinita Gupta: We just sent CRL full response last quarter. And our TAD date is August of this year.

Anubhav Agarwal: Okay. Thank you. I'll join the queue.

Moderator: Thank you. Next question is from Neha Manpuria.

Neha Manpuria: Yeah. Thank you for taking my questions. Ramesh, if I were to just look at operating cost, in this quarter, given that we had one-time impact from restructuring in the last quarter, if I adjust for that, operating costs haven't really changed quarter-on-quarter, despite, optimization efforts you mentioned that we have taken and the restructuring in specialty. So could you give some color on when we will start seeing that improvement? And despite the restructuring effort, we haven't seen it in this quarter, what gives you the confidence of improvement going forward?

Ramesh Swaminathan: This quarter we had in fact the higher quantum of R&D, so to that extent that's been captured out here. Going forward that bit will not be out there. We also spoke about the fact that we speak about the manufacturing and other expenses, we are looking at in fact NCE spin-off itself and that we are fairly confident will certainly happen over the next few quarters that will be the other bit. And of course, as I said, other initiatives that we are really taking.

Neha Manpuria: Ramesh, sorry, just to understand the NCE spin-off, it would be an R&D savings largely, right? Besides that, would it materially change our EBITDA margin besides the R&D savings?

Ramesh Swaminathan: so we are spending close to INR150 crores to INR200 crores on NCE. So, if, when the spin off actions that would actually be off at least the EBITDA.

Neha Manpuria: Okay. Understood. And second on the U.S. business, from the current $800 million base given the price erosion that we're seeing in the launch pipeline. From a two to three year perspective, what is your comfort and what this number could look like based on the pipeline that we have, especially since you're mentioning a very large inflection in FY24? And also, just a follow-up on that on biosimilar besides take Peg-GCSF, if you could just give an update on your second biosimilar. Ranibizumab

Vinita Gupta: Yeah. So in terms of the new product launch, really second half of next year, as we mentioned Suprep, Tiotropium, hopefully Pegfilgrastim as well and partially or impact obviously in just FY23. But a full-year impact we see in FY24, which gives us the confidence of really growing the U.S. revenues in a material manner and in the commensurate increase in gross margins and contribution to EBITDA margins as well.

I was saying that, it's on the biosimilar front, of course, pegfilgrastim is a lead into the U.S. market: Etanercept is growing. Mylan has a launch plan across all of the different geographies, most recently, they launched in France. And ranibizumab is progressing, I mean the clinical trials, Phase 3 trial in India is progressing, well. There were some delays from a COVID perspective, but we're still making progress on the trial.

Neha Manpuria: Sorry, when would be the filing for this likely filing for ranibizumab?

Ramesh Swaminathan: In the upcoming fiscal

Neha Manpuria: Got it. Thank you so much.

Moderator: Thank you. Next question is from Surya Patra.

Surya Patra: Yeah. Thank you. Thank you for taking my question, ma'am. So first, see if you can tell me, what is the kind of progress that we are witnessing in case of Fostair in Europe.

Vinita Gupta: Sure. So, I mean, we've had really good progress in terms of contracting with the physicians, our CCGs that are important to drive utilization of the product. We have seen some uptake, but not to the level that we had expected due to the COVID surge, the Omicron surge in UK, majority of the CCGs are focused on treating COVID at this point. So, we expect the utilization to ramp up over the quarters to come, especially now that UK has also opened up quite a bit and relaxed their restrictions quite a bit as well. But we've had really good success in contracting, both with the writers, the physicians, as well as the retailers.

Surya Patra: Okay. Based on the contracting, can you share what is the kind of market share now practically that you are witnessing, let's say, over the next 12-month period.

Vinita Gupta: I wouldn't be able to state, maybe we can get that to you offline.

Surya Patra: Okay. Sure. Now, my second question is on the margins again ma'am. Practically, we have seen a good ramp up in the albuterol, obviously, some contribution would be coming from the Fostair and all. So, despite that the margin scenario remains really weak and we are possibly guiding a lower margin again. So, this is the third time that consecutively we are indicating a lower margin scenario. So, from the 17%, 18% level, we have brought down to

16% for H2 and now 14% that kind of a number that we are indicating. So, what is that is really driving down whether the pricing scenario, what we have agreed for albuterol that is much lower what we have been anticipating. And if these products are not contributing to the overall profitable growth, then we should ideally be witnessing or waiting only for Spiriva to really contribute.

Vinita Gupta: Yeah. So, to your point, albuterol is actually contributing very nicely to growth in revenues as well as in margin, offsetting actually a lot of the other price erosions that one is witnessing, which is part of the baseline business. We actually expected even higher revenues both in the U.S. as well as in the API business, which suffered due to the seasonal products. So, when you look at the seasonal products, Tamiflu as well as the Cephalosporins, we were expecting at least some flu seasons, like, but haven't seen any whatsoever, you know. It's then because of protection, people are masking off, which is protected, but it's also having an impact on the flu season and flu products. So that's why, if you from a business perspective, revenue perspective, we would have been even higher in the US, if you had the flu season as we were anticipating, in this past couple of months.

Surya Patra: Just last question, ma'am, on let's say, slightly futuristic. See, given the kind of a price erosion scenario that we are witnessing in U.S. which is the largest market -which has been the largest market for us. So, are you really bothered about it that means the overall growth for the business would be impacted by the larger business, which is facing challenges? And lets say three year down the line, what share of revenue that you will really looking from U.S? Or your effort from the other market non-U.S. market would be rising significantly and possibly would be supporting the overall growth for you.

Vinita Gupta: Yeah. So, thank you for the question, because I think, when you start looking at it from a three-year perspective, one can also look at all of the results of the efforts that we have put in over the last many years. And on the one hand, while we're going through the inflection from the simpler genetics to complex generics right now with albuterol and inhalation portfolio and seeing the business kind of stabilize right now, we would like to be able to deliver a higher level of revenues and margin growth, but just given that we have just albuterol and Brovana, small Fostair is still not a contributor, we see this transitioning over the next couple of years, as we see the full impact of inhalation pipeline, as we see the full impact of, well, that you haven't seen much impact of our injectables portfolio, but have really great filings at this point with products like glucagon, ganirelix, and the like, and more coming. And products like pegfilgrastim that we hope to launch in FY23 and have a full-year impact on FY24.

As an organization, we are not nervous about increasing the U.S. revenues. I mean, we have the potential of growing in the U.S. outpacing other markets with product that are going to be more profitable than our baseline products. Already we are seeing that the albuterol margins are, inhalation product margins are higher than obviously the oral solid margins. And as that component of the business changes and revenues grow, we should be able to grow both the company top line with the contribution of the U.S. as well, as margins.

I'd say that the revenue mix should roughly be the same. There shouldn't be a material shift we have I mean, very solid growth, double-digit growth in India, on a consistent basis, we expect to continue that years to come and the U.S. will start with the next fiscal year half-year impact. So, a lower growth level, but a higher growth level in FY24 and FY25, but roughly the same level, same mix of the major businesses. The other businesses also, the other markets,

we are working on growing scale and operating leverage in the most prudent manner. So, but they are smaller at this point relative to the U.S. and India.

Surya Patra: Sure ma'am. Thank you. Wish you all the best

Vinita Gupta: Yeah. Thank you.

Moderator: Thank you. Next question is from Vishal Manchanda.

Vishal Manchanda: Thanks for taking my question. On gross margin, can you break it up as to what is raw material inflation impact and what is the business mix impact?

Ramesh Swaminathan: Yeah. So, the overall impact is essentially you can say about a half a percentage point is essentially because of inflation. And the balance is essentially because of the sales mix itself.

Nilesh Gupta: Yeah. Another 0.3% is the sales mix.

Vishal Manchanda: Okay. And on the R&D NCE spend INR150 crores to INR200 crores is the quarterly number. Is that right?

Ramesh Swaminathan: That's annual number.

Vishal Manchanda: That's the annual number. Okay. And just one final question, in India, what percentage of revenue would be from in-licensed innovator brands?

Ramesh Swaminathan: About 15% to 16%.

Vishal Manchanda: Got it. Thank you.

Moderator: Thank you. Next question is from Pratik Kothari.

Pratik Kothari: Hi, thank you for the opportunity. A couple of questions on the U.S., one, on the base, are we still seeing those high single-digit pricing pressure? And second, our expectation was once we cross this $200 million there we should see some massive operating leverage coming, but we haven't seen that, so just your comments on the same.

Vinita Gupta: So, the pricing pressure is here to stay. I mean, it's become part of life in the generic business. And we really see it changing materially when the business transitions more towards complex generics. The oral solids unfortunately have too many competitors. So, one has to constantly be working on, trying to gain share there, but it's logical to gain share and reduce cost on all the products while grow the business with new products. What was the second part of your question?

Pratik Kothari: Second one was, once we cross this $200 million of quarterly revenue, we should see some massive operating leverage in the U.S., but we haven't seen that, so your comment on the same.

Vinita Gupta: Yeah. So, I think the operating leverage is going to come from some of the efforts that we have underway way that we are talking about. I mean, we have, from optimization standpoint worked on multiple areas so far the right sizing the U.S. team as well as looking at any other areas of revenue or profit leakage, whether it's FTS or returns and write-offs. A big part of operating leverage is also going to come from plants which, right now are due to all of the challenges that we have had in the last couple of years with OAIs and the fact that new product launches have struggled.

We see that the idle cost in the plants have don't have gone up significantly and has really burdened the P&L quite a bit. But with the efforts that we have underway on the optimization in idle cost as well as continued increase in volumes from the products, that now with Goa having cleared the FDA this last quarter, we expect seven launches out of Goa, not big launches, not like Suprep and Spiriva, but still contributing to revenues and reducing idle costs on top of our optimization efforts on plant overheads and idle cost. So, you're going to see more of that operating leverage coming both from the optimization efforts as well as continued increase in volumes with new product launches.

Pratik Kothari: Fair enough. And given that we are pushing our 20% plus EBIDTA margin another year, so where do we stand when it comes to FY23?

Vinita Gupta: For FY23, we see like Ramesh mentioned, in the next couple of quarters, really more of a margin contribution optimization effort. It's really second half of the year where we have Suprep, Tiotropium and hopefully Pegfilgrastim FDA inspection permitting coming in that will allow us to ramp it up.

Pratik Kothari: Fair enough. Thank you and all the best

Moderator: Thank you. (Operator Instructions) Next question is from Kunal.

Kunal Randeria: Hi, good evening. And thanks for taking my questions. Vinita, when you say, you have 20 exclusive FTFs can you provide a bit more color on how the launch are spaced out? And are any of these currently being held back because of regulatory issues at your plant?

Vinita Gupta: I'll take the second question, yes, some are being held back, but we are actively tech transferring them into other sites, so that we risk mitigate there and be able to unleash them in time. They are spaced out actually, if you start looking at FY23, you have two big ones, both Tiotropium as well as Suprep, where we are exclusive first-to-file. And then in the years to come, those are the two big that come to mind in the next fiscal year. And we have other products like Tolvaptan that's the material oral solid first-of-file. That's out, I think in FY25 not '24. So, it is spread out over the next FY23, FY24, FY25.

Kunal Randeria: Sure. So, all these 20 will be in the next three or four years?

Vinita Gupta: No, no, I won't say that. We can try to get you the actual spread over the next three years, the next five years and beyond.

Kunal Randeria: Well, that would be great. Secondly, Vinita, actually, you had mentioned, I think you had submitted Dulera I think almost 18 months back. Could you share where you on this product now? Because I think you had mention FY22 launch earlier, so are you sort of still confident of that launch?

Vinita Gupta: No. Not FY22 obviously, because we're finishing FY22. We've had our CRL. We've received the CRL from the agency that was fairly intense. We have put together a response, which is going, I believe in the next couple of months. And hope that we can get approval in the next fiscal year. But we are going to wait to see how the agency is responds to our CRL response.

Kunal Randeria: Right. And what kind of competitive intensity do you see when you eventually launch the product?

Vinita Gupta: So far we haven't seen any material competitive actions. We haven't seen PD studies, alternate studies that we track. So, we still think that it's a very nice niche product for North America.

Kunal Randeria: Sure. And just one more, are you close to settling on Revlimid?

Vinita Gupta: Oh we settled.

Kunal Randeria: Oh you have already settled. Okay. Can we expect a sort of Q4 FY23 kind of a launch?

Vinita Gupta: No, no, we wouldn't. We actually saw a lot of risk there

Kunal Randeria: Right, right. Okay. Thank you very much for answering my question and all the best.

Vinita Gupta: Thank you

Moderator: Thank you. Next question is from Anubhav Agarwal

Anubhav Agarwal: Yeah. Hi. Two, three questions. First on the India business. Any material move planned by you guys to boost growth in the India business? For example, increasing sales force for looking to aggressively develop some new therapies, because if, U.S. is what it is, right, so, I'm just trying to say that, what are we trying to de-risk our business and grow the most predictable part of the business?

Nilesh Gupta: Sure. I can take that. First of all, I do want to say this on the U.S. So, I think while we need a little bit of a breather, we feel pretty good about some of the growth drivers that we're putting in place in the U.S. and while we're over the $200 million number right now, some of it is coming from these partner products and the like, obviously the margin profile there is different from our own portfolio. So as the inline portfolio picks up, as the Cefs pick up, as more of Goa and other products come to market, I would expect that the U.S. margin profile could improve.

On India, I think that's our second biggest market. Obviously, a market we bank on, a market in which we are in number six, obviously there is significant headroom to grow. Anubhav you know our focus has been on the chronic side, the market is two-thirds acute, one-third chronic, we are the opposite by design. And we have two therapies, over INR1,000 crores, we have another therapy over INR500 crores and so much headroom to grow. On the chronic side, we're number four, while overall we're numbers six, we add the opened up one new division last year. There is a program few hundred representatives that we keep adding each here, so next will be an additional respiratory division and other divisions as well as.

I think we're still under indexed in multiple therapy areas, like dermatology for example, or even in the CNS space, there is room to grow. So, lots of room to grow. As you know, I think we're starting a little bit in acquisitions India as well. So, we talked about Anglo-French. Obviously, we hope to close that soon. So, a lot of headroom to grow and we're obviously pushing to grow. We're also exploring adjacencies, like diagnostics early days, right now. But I would say that, I think on the U.S. complex generics, that's where we press the accelerator, on optimization, we press the accelerator as well, and on the India region, we obviously press the accelerator as well, so all three are going strong.

Anubhav Agarwal: That's great. Thanks Nilesh for that. Just a couple of more clarities on the U.S. business run. On the injectable portfolio, how many filings have you already made so far?

Vinita Gupta: We have made 10 filings, Nilesh

Nilesh Gupta: Yeah. I think under seven or eight, but yeah, thereabouts. But I think we're also on track to file six odd products from India, which are, I would say about medium complexity kind of products, and hopefully we'll file the first of our Nanomi products in the upcoming fiscal as well.

Anubhav Agarwal: So without those long-acting injectable, for example, if we just keep them out, the other injectables, let's say, if we take a period of three, four years, how big this portfolio you think on a conservative basis can become?

Nilesh Gupta: So, at least six plus products filing every year and adding the first product that we launched will be the products that will come under that products, like glucagon, products like liraglutide and the like. So, that's why I said medium complexity. I think these will all be great products from us from a launch perspective.

Anubhav Agarwal: Okay. And on generic of Restasis I think you guys are working one seven years back you've been be able to file the reformulated version, are you there in this opportunity or not?

Vinita Gupta: Yeah. We're not going to approval for the product as of yet.

Anubhav Agarwal: But are you following that activity?

Vinita Gupta: We are.

Anubhav Agarwal: Okay. And Ramesh, just a couple of clarities. The other operating income was pretty high this quarter as well. So, the usual run rate is about INR35 crore a quarter, you're being about INR74 crore to INR75 crore, what is a level that we should assume in next two, three quarters?

Ramesh Swaminathan: That's essentially coming in from settlements. So, to an extent, it is sporadic in that sense, it's difficult to actually predict it.

Anubhav Agarwal: But should we keep building the base as INR35 crore.

Ramesh Swaminathan: Yeah, that for sure

Anubhav Agarwal: And for the next quarter, will there be extra pressure from the increase in raw material cost?

Ramesh Swaminathan: There has been considerable pressure in recent times, as you would recognize across industries and the sector as well. So, yeah, you could build in a 0.5 percentage point at least.

Anubhav Agarwal: And so, would quarter four margin there could be lower than what we had? Or your other savings could largely fortify them?

Ramesh Swaminathan: In the vicinity of where we are today, I would say.

Anubhav Agarwal: Okay. Thank you guys.

Moderator: Thank you. Next question is from Sameer Baisiwala.

Sameer Baisiwala: Hi, good evening, everyone. Just a quick question on the margins, if I'm not wrong, in the previous quarter you had guided for 17% to 18% EBIDTA margin for H2 FY22. So, what has changed within the quarter two, three months that our expectations came down so much.

Ramesh Swaminathan: Yeah. Sameer, I'll take the question. So we had indeed said that the second half would be better than the first half and we could look at around 16%. Well, sequentially U.S. has indeed grown, but we had higher than expected competition in Famotidine, lower sales in Glumetza than expected and the like. We were also expecting some flu season, which would have resulted in higher sales of Oseltamavir that's not the case. There is change in business in a lower sale in India that has impacted and of course the inflationary pressure that is actually come in. For those reasons, there has been some impact.

Sameer Baisiwala: Sure. Just a very broad question, most of the companies your size in the sector have margins anywhere from 20% to 25% or maybe even higher percent and we have been sub 15% for pretty long now, it is structurally that is out of place that we are not able to get it back even to 18% 20% and it's a big effort. Your sales mix is pretty much same as others. So, I'm just wondering, what's that impediment to get the margins to more normalized levels?

Ramesh Swaminathan: Sameer. I kind of said that, right, I said, there are some inefficiencies that have kept up the system over time. We have also invested ahead of the curve in terms of at least capacities, leading to the quite some idle time and the like, inefficiencies in the form of FTS for sure. We also had issues in terms of returns. Then of course in our freight, air freighting and stuff like that. All of these things we are addressing. Especially, when it comes to manpower, it's not an easy question to solve, it could take time, and that's one of the reasons why we said for the next couple of quarters, next three quarters, you could expect the lackluster results. And things would certainly look-up after, towards the third or fourth quarter of next year.

Vinita Gupta: If I can add to that. Sameer, structurally, what is different is I think our investment on the R&D front is higher, than our peers. I think we have invested in more platforms that have yet to deliver. I mean whether it is the, I mean, so inhalational is started to, injectables has yet to, biosimilars has yet to in the material manner, specialty obviously we optimized, NCE we want to spin out. But right now the investment is, the number is within our R&D spent. So, I'd say higher R&D spend and as Ramesh said also, high investments in facilities, some of which again for these products for the future, but some idle cost that has gathered over time that due to new product launches not happening due to our OAI warning letter status. So, that portion, we are correcting, of course, but as we continue to really launch a product from the new

platforms and our optimization efforts, when we look at FY24 for example, when we have Albuterol, Tiotropium, Pegfilgrastim, few products are not just one or two, but three, four products, five products on the complex front in the market. We really see both from a revenue and gross margin pricing standpoint that upside as well as capacity utilization standpoint operating leverage.

Sameer Baisiwala: Yeah. Thanks for this Vinita. And just a couple of product related questions. One is on Tiotropium. So for our comparable device Handihaler. What do you think is the addressable market the net brand sales is it like roughly $800 million.

Vinita Gupta: Yes, close to a billion.

Sameer Baisiwala: Okay. And if you are the only generic there, what is the sort of a market share expectation, I mean, the range is it 20-30 or 50-60, if you can help with that.

Vinita Gupta: Sameer, you know our typical market share in products where we are semi-exclusive along with the AG its 50%, at least.

Sameer Baisiwala: Okay, great. And the second question on Revlimid. So, are you saying that it's not going to happen in FY23, it's beyond that, is it?

Vinita Gupta: That's right. We saw risk in launching a limited quantity authorized generic. We saw risk in the potential launch in the near-term.

Sameer Baisiwala: Okay. So is it like middle of FY24 something or?

Vinita Gupta: I think it's FY25.

Sameer Baisiwala: Okay. Got it. Thank you so much.

Moderator: Thank you. Next question is from Mr. Prakash. Please unmute yourself and ask your question.

Prakash Agarwal: Yeah. Good evening. Question to Nilesh for the Goa plants, congrats on clearing it finally. But what is our learning their A, B, what is our discussion for the Pithampur and the other facilities, which are still having because Goa also had out of specification issues and you had similar issues in the other plant. So, what is the dialogue which is on and when do we expect the next level of inspections for other facilities?

Nilesh Gupta: Thank you for that question, Prakash. So, we obviously feel very good about the change in status of the Goa site. I think we have warning letters started with Goa, so it's only fair that they should end with Goa, heralding that. I think, you're absolutely right, I think the issues that had in Goa were similar to what has been sighted in the past as well. And I think, I'm very glad that the agency seems to have noted the steps that we've taken. And I don't think we're done with that. I think we see that we're clearly on the right path, especially as far as investigations are concerned. And that is the same system that they would see at any of our other sites as well.

Obviously, each inspection is different, it's a different set of investigators who would come, we already know that there is not going to be remote audits. So, I think Omicron has played a little bit of spoilsport on the inspections. So, I think it's possibly a few months before which you can expect predictably inspection starting again. And but we're ready, as far as Pithampur is concerned, or Tarapur is concerned. We're ready. It's the same system in those obviously we remediated on the other items that were highlighted in the past. So, I feel much more confident. The confidence that I get from our team is much more. I think our team did it well, clearly Goa points that we're moving in the right direction. And then now we would want to get even better at things like investigations and what we already are. So, I think we're moving in the right direction. We have a stated goal in the next 18 months to clear all our sites. And I hope that we're going to be able to deliver on that.

Prakash Agarwal: Okay. And from your journey from today to the 20% margin that you're talking about, so where you have built-in this in terms of resolution of your larger facilities Pithampur, I mean 18 months is a pretty long time, right?

Nilesh Gupta: So, I think, the one good thing is that the railroad drivers they've all been protected. They've all been inspected separately and all those inspections have gone through fine. So, if you see inhalation, for example or even smaller platforms like Derm, for example, biosimilar records still needs to be really inspected as does injectables. But these problems that we had on the oral solids at sites like Pithampur Unit 2 or Goa or even on API interface with Tarapur, didn't translate into disrupting that kind of growth.

So, I think the bigger products are protected anyway, and it's a question of time to be able to deliver them, like Vinita said Suprep will be sooner, Tiotropium will be a little later, but it's all coming together in H2. You do see that increase happening. There's some 20 odd products that will get launched from Goa over time about 7 or 10 of them are ones which were really stuck only for site related issues. The others have some more things as well. So, those will come, like, Vinita said, they're not going now be big products. But I think it's those couple of million dollars that you get from each of these products that helps grow the business.

We've had a pitiful launch story and I think that's really vitiated the nature of the generic business in the U.S. And I think it's high time that we get that back on track. The backlog in Pithampur Unit 2 is even more than what Goa had. So, we're looking forward to that clearing and then starting to get more approvals from there as well.

Prakash Agarwal: Thanks for the elaborate answer. My second question is on your thought process on building or rebuilding the specialty portfolio. So currently we are on thin margin, so, what are we thinking about investing for the next phase of building specialty in the U.S?

Vinita Gupta: So, a couple of areas that we're looking at. One, we have really de-risked our P&L for the women's health, right, from a commercial perspective and have partnered Solosec with a really good women's health company and Exeltis that has 120 people sales force. That's what we had at peak, when in the first year Solosec was what tracking at $10 plus million in revenues, so we're very hopeful that with the kind of strength that they bring to Solosec we will be able to do justice to the product and decent level of revenues, and profitability

obviously to be shared with them, for the fact that they are putting the promotional effort behind it. So, one is that on the commercial front.

Second, we have builds capabilities on the R&D front, on the technology front and IUDs, implants and rings and have three products in development right now that will continue to pursue. And they will take time because each of them is a drug device combination. Implants, rings require clinical studies. So, it takes a little bit of time. It will take two years, but we see the potential of getting these products to market, within a four-year time frame. So that is one on the women's health front.

Third, we are looking at other platforms, we have our neurology product Namuscla in Europe. We're looking at the potential of bringing it into the U.S. market. Fourth, looking at respiratory, which is now become the largest part of our business in the U.S. with Albuterol and Brovana to look at areas of unmet needs where we can bring in our own products from organic R&D standpoint.

And fifth, on the injectable front, where there is tremendous opportunity and the companies like Eagle and others have capitalized with the capabilities that we have now developed around injectables and peptides and colloids and long-acting injectables. We expect to bring in some innovative products. In fact, we have partnered with a company on NDA for Fosphenytoin, which is going to be our first 505(b)(2) injectable product. We expect to launch not in FY23, I think it will be tech-transferring in FY23 but in FY24. So, we're looking at multiple areas and will continue to be both opportunistic as well as proactive in evolving a pipeline.

Prakash Agarwal: Perfect. And with your permission one clarification. So, I mean all the questions are routing through the gross margin thing and the guidance of EBITDA margin of 16%. So, the reasons you gave on lower Glumetza and lower flu et cetera, Famotidine and stuff. So, these are all known variables. So, what has really changed going down 200 basis point? If you could help us to understand that.

Vinita Gupta: Yeah. So, the material variable really were the flu products as I mentioned, and we were expecting reasonable flu season, which we haven't seen any. And, also the increase in input cost material that has been the pressure has been higher than we expected.

Prakash Agarwal: Okay. Thank you and all the best.

Vinita Gupta: Thank you

Moderator: Thank you. Next question is from Aditya Khemka

Aditya Khemka: Yeah. Hi, thanks for the opportunity. Any timelines you would like to share on the spin-off of the innovation R&D business? And would the structure be that every shareholder of Lupin will get one share of the innovation entity as you have seen with some of your other companies.

Vinita Gupta: Yeah. So, we are actively working on it right now, hopefully, in the next couple of quarters. And we are in active dialogue with firms to see, how we can bring in third-party investors into the entity. Right now, it is 100% subsidiary of Lupin, so full value. And the full is within Lupin

and our plan would be to continue to maintain Lupin shareholding into the entity. So, we don't expect to split it up. Ramesh correct me if I'm mistaken.

Ramesh Swaminathan: That's true

Vinita Gupta: The value to our shareholders is really going to be through Lupin and Lupin shareholding in the entity.

Aditya Khemka: Got it. It helps. Secondly, on the Capital Expenditure side. So, since we have a lot of spare capacity and we're lacking sort of approvals. What is it that we are incrementally spending the Capital Expenditure on and what is our Capital Expenditure budget for FY22 and FY23?

Ramesh Swaminathan: A chunk of it is actually going to maintenance and of course there's something to be built for biosimilars and as and when they improve. And essentially that really. Not too much in new capacities being built at this stage.

Aditya Khemka: And the budget, Ramesh sir for FY22 and FY23.

Ramesh Swaminathan: It will be in the ballpark of INR500 crores, INR600 crores max, everything put together.

Aditya Khemka: Got it. And I missed, maybe if you talked about the India acquisition and your recent foray into diagnostic. So, Nilesh would love to hear your view on. What is the quantum of sales that we acquired? How much have we acquired is for? What is the kind of synergy you expect? And if you can talk about the diagnostic foray as well. Thank you.

Nilesh Gupta: Sure. Anglo-French roughly about INR95 crore sales, I think we talked about the fact that it's approximately INR325 crores in cost. It will be accretive from day one. Basically, it's two big products that really helps us build in the vitamins, minerals, supplements, segments: Beplex and another product Nitravet. In the VMS segment, it will take us from number 18 to number 11. So, obviously a nice move and we're hoping that by March, we should be able to close it.

Diagnostics, I think, early days to talk and we just launched the business in December. We've got three or four labs right now. Another three or four labs that we're managing. Q4 will see a major ramp up, we'll see another eight labs coming up there. They're already a couple of 100 collection centers up. I think the next year will be the defining year for that business. We're seeing nice traction at this point of time, but very small in the Lupin scheme of things. I think 12 months from now, it will be a great time to talk more about diagnostics.

Aditya Khemka: Yeah. Okay. Thank you.

Moderator: The next question is from Krishnendu Saha. Krishnendu, if you can just unmute yourself and ask your question.

Krishnendu Saha: Just on the diagnostics, does your margin improvement take into account all the expenses, which you will incur for it and just curious to know when do you think Goa plant will start getting approvals with the VAI, so when we think that? And the third question is how much of

the idle cost is being saved if things come into place with time. So, there are couple of more questions, but we are short on time so you can just give me these numbers.

Nilesh Gupta: So, yes, we have taken the diagnostic business spend in the overall India region plan as well and we still expect to deliver on the EBITDA improvement. The burn is not that high. There will be a burn increase, but they'll be more than commensurate increase in the Indian region profitability, that would happen anyway. On Goa, we already had one approval as you know, and that product is getting launched shortly. There are another 6-7 products that we would expect to get approved in the upcoming fiscal and those will get launched as well. And then, I think this approximately about 20 products that are still pending from Goa. On the idle cost, first of all, idle cost is never going to be zero. It obviously needs to be optimized. What has happened right now is demand is significantly down for multiple product categories, the Cefs, for example, both API and finished products for some of the other products as well. And I think that is accentuating the idle cost right.

Obviously, the other part is sum of the capacities that we've created for new growth drivers, which are not kicked in. So injectables, for example, which is still not inspected, biotech where it's still not adequately utilized. So, those would add to the item idle cost as well. And part of our optimization is going to be increase in revenues of some products to optimally utilize our capacities. But the other is actually going to be workforce planning around some of the plants as well, where we don't see meaningful uptick over time. And that is something that we are expecting to close in the next three to four months after which you'll start seeing benefits of that.

Krishnendu Saha: Sure. Is there is a number you can share with us? And would you in the future, would you be separating the diagnostic business numbers and the Pharma business numbers?

Nilesh Gupta: So even now, the diagnostic business number is reported separately because it is a wholly owned subsidiary of Lupin. We will be calling it out.

Krishnendu Saha: Sure. Thanks

Moderator: Thank you. The last question is from Vishal Manchanda. Yes, Vishal please, unmute yourself and ask a question. Okay, I think Vishal is not here.

Nilesh Gupta: I think Tushar has question as well, you can take that.

Moderator: Yeah, please. Tushar, you can ask your question.

Tushar Manudhane: Thanks for the opportunity. Sir. there is a bill with respect inspections going in a surprise way, I mean, all inspections going in a surprise way rather than scheduled. Do you see this as a risk? And so then how do we call you able to mitigate?

Nilesh Gupta: So, I think that's the stated intend, that's in that bill, we'll see what happens on that count, in any case pre-COVID there was really no notice period that was given other than VAI and inspection for new facilities, regular surveillance inspections for a while. Although, it is a pilot in India, but I think for a while regular inspection were happening, but I don't think it makes a

difference whether you may notice period, or no, notice period, or one month notice period, there isn't much that you can do because everything is data, everything is record, which are available now.

Tushar Manudhane: Secondly, on this API business we've seen huge amount of deceleration now for four quarters. So, anything specific, structurally things not going away or how do we look at the sales going forward?

Nilesh Gupta: So, I think the API business has been very challenged at this point of time with the lack of demand in cephalosporins coupled with the increase in Pen-G prices. There's margin pressure. But really there is no demand for cephalosporins at this point of time. We obviously see that normalizing and with that will come meaningful increase in API sales as well. Right now, my feeling is that, that is really Q2 and beyond. I don't think we see it in the next three, four months as a meaningful up take.

Tushar Manudhane: Got it, sir. And just lastly on other expenses excluding R&D, while we have been working on the cost optimization measures, but on an absolute basis, other expenses, excluding R&D and employee costs still continue to rise even sequentially, it's higher even after adjusting for the one-time expense related to Metformin, and the other product. And given that you have this marketing expenses on the domestic formulation on this inorganic part as well as ramp up of other diagnostic activities. So, how do we see on an absolute basis these are expenses, reducing by 1-2% going forward?

Ramesh Swaminathan: Yeah. There is actually several line items that have been combined in there, so you're right about the fact there is Diagnostics and other expenses also, so to the extent, we need to really look at each item. We will take the top-line for sure, but we are working on a number of initiatives at this time.

Tushar Manudhane: Sure sir. But any ballpark number, like, by what percentage do you intend to reduce this?

Ramesh Swaminathan: It would actually all feature ultimately in the EBITDA improvement, right? So, irrespective of what is the absolute number itself that we have taken in saying that the EBITDA improvement will take place in the time period that we indicated.

Tushar Manudhane: All right sir. That's it from me sir. Thank you a lot.

Moderator: Thank you. We'll take the last question from Mr. Vishal Manchanda. Vishal if you can unmute right now.

Vishal Manchanda: So, sir, just wanted to check whether levothyroxine is still an important product for you in the U.S?

Vinita Gupta: It is.

Vishal Manchanda: Okay

Vinita Gupta: We have 17-18 % share of the market.

Vishal Manchanda: Okay Got it. And it is a meaningful percent of your overall US Sales?

Vinita Gupta: Our Largest product is Albuterol. Levothyroxine smaller than it was in the past, with the competition we have seen in the past 12-18 months, but still a material volume product.

Moderator: Thank you. That was the last question. I now hand the conference over to management for the closing comments.

Kamal Sharma: Well, thank you everyone for your active participation, very useful some the questions that you raised and look forward to seeing you in the next quarter. Thank you once again and take care of yourselves and your families. Thank you.

Moderator: Thank you, sir. On behalf of Lupin Limited, that concludes this conference. Thank you for joining us. And you may now disconnect your lines and exit the webinar.